

soluble fraction. Moreover, Applicants' representative directed the Examiner's attention to page 7, lines 4-12 of the specification, which indicates that the present invention proposes a novel fractionation method wherein protein fractions having characteristic features with less contamination are achieved.

The Examiner kindly indicated that these arguments may be persuasive in overcoming the outstanding rejection. She suggested that Applicants present detailed comments in this regard in a response to the Final Rejection, at which time she will carefully consider the same.

Applicants submit herewith comments along the lines of the arguments set forth during the interview with the Examiner. Favorable reconsideration is respectfully requested in view of these comments.

Lastly, the Examiner kindly indicated that she would contact Applicants' representative in the event that the comments presented herein are not deemed persuasive in overcoming the outstanding rejection.

Rejection Under 35 U.S.C. § 112, First Paragraph

Claims 1-4 are rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. The Examiner refers to the proviso in claim 1 that neither a sulfurous acid nor sulfite is added to the solution. The Examiner takes the position that the instant specification does not appear to have explicit support for said proviso.

Applicants respectfully disagree with the Examiner's position.

Initially, as explained in the second paragraph on page 3 of the response filed March 1, 2010, support for the proviso language is set forth on page 3, lines 21-23 and page 4, lines 14-16 of the specification. Specifically, as discussed above, the specification explains a problem with the prior art method when a sulfurous acid compound is added. In the paragraph spanning pages 3 and 4 of the specification, a method is described which utilizes a phenomenon that the solubility of 11S globulin is lowered at a low temperature, and a soybean protein raw material is treated in the presence of a sulfurous acid compound, followed by adjusting the pH to 5.5 to 7.0 and the temperature to 22°C or lower to fractionate into a 7S globulin-rich soluble fraction and an 11S globulin-rich insoluble fraction.

In the first full paragraph on page 4 of the specification, a problem regarding this method is discussed. Specifically, cryo-precipitation phenomenon is highly dependent on temperature and it is necessary to cool the reaction mixture to about 5°C, which results in such a practical problem that a large amount of a sulfurous acid compound should be added to separate fractions with an industrially available low centrifugal force, as well as which results in such a problem of fractionation precision that a little amount of 11S globulin is contaminated in a soluble fraction.

In the first full paragraph on page 7 of the specification, an object of the present invention is described, i.e., providing protein fractions having characteristic features with less contamination and high purities of 7S globulin and 11S globulin.

Accordingly, although the explicit language of the recited proviso is not included in the specification, it is quite evident from the above descriptions that the subject matter of the proviso is clearly supported by Applicants' specification.

MPEP 2173.05(i) indicates that the lack of literal basis in the specification for a negative limitation may not be sufficient to establish a *prima facie* case for lack of descriptive support.

Additionally, MPEP 2163 states that: "If a skilled artisan would have understood the inventor to be in possession of the claimed invention at the time of filing, even if every nuance of the claims is not explicitly described in the specification, then the adequate description requirement is met. See, e.g., *Vas-Cath*, 935 F.2d at 1563, 19 USPQ2d at 1116; *Martin v. Johnson*, 454 F.2d 746, 751, 172 USPQ 391, 395 (CCPA 1972) (stating 'the description need not be in *ipsis verbis* [i.e., "in the same words"] to be sufficient')." (Emphasis added.)

Accordingly, Applicants respectfully assert that the specification clearly provides support for a method wherein neither sulfurous acid nor sulfite is added to the solution, based upon the discussions of the prior art where the addition of a sulfurous acid compound is detrimental, i.e., causes contamination, and based upon the discussion of the present invention describing a novel method which achieves less contamination and higher purity. In view of the above, it is respectfully requested that the above-rejection be withdrawn.

Consideration After Final Rejection

Although these remarks are presented after final rejection, the Examiner is respectfully requested to enter and consider the remarks, as they clarify that the application is in condition for allowance.

Conclusion

Therefore, in view of the foregoing remarks, it is submitted that the ground of rejection set forth by the Examiner has been overcome, and that the application is in condition for allowance. Such allowance is solicited.

If, after reviewing this response, the Examiner feels there are any issues remaining which must be resolved before the application can be passed to issue, the Examiner is respectfully requested to contact the undersigned by telephone in order to resolve such issues.

Respectfully submitted,

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